CHANGES TO PRESCRIBING AND DISPENSING CONTROLLED SUBSTANCES

Effective January 1, 2005, all written prescriptions for Schedule II-V controlled substances must be on tamper-resistant prescription forms. (Health and Safety Code section 11164.)

The use of serialized triplicate forms for prescribing Schedule II controlled substances has been terminated by legislation amending Section 11164 of the Health and Safety Code. It is important that all prescribers who issue Schedule II controlled substances purchase tamper-resistant forms in order to be in compliance with Section 11164 of the Health and Safety Code. By complying with the new legislation, each prescriber will be able to continue uninterrupted care for their patients and their medical emergency needs. (Health and Safety Code Section 11164 continues to allow the dispensing of Schedule III -V controlled substances upon an oral or electronically transmitted prescription form.) To inquire, or access by e-mail, a listing of state approved security printers or for further information you may utilize the Attorney General's web-site (www.ag.ca.gov) or contact the contact the Department of Justice CURES program at (916) 319-9062.

Prescribers finding themselves without the tamper-resistant forms will encounter challenges in providing optimal care to their patients. Prescribers should not utilize Section 11167 of the Health and Safety Code to avoid complying with the new law. This provision only allows for emergency filling of Schedule II prescriptions without a prescription form when failure to issue a prescription may result in the loss of life or intense suffering. Reliance on this provision was allowed during the fall of 2004, during the changeover period to allow prescribers the opportunity to obtain the new tamper-resistant forms. During this period of time, prescribers were allowed to make the notation of "11167" on prescription forms, and pharmacist were asked to make exceptions to the special form requirement. That allowance is no longer in effect.

The Department of Justice (DOJ) acknowledges that critical emergency care and loss of life are a public safety concern and presumed when this provision is utilized without a prescription form. However, use of this provision must be medically necessary and utilized in good faith by a prescriber/practitioner and should not be exercised as an ongoing practice by delaying the purchase of the tamper-resistant forms or by avoiding their use, which would not be in compliance with Section 11167 of the Health and Safety Code.

For those prescribers who are still in possession of triplicate forms, the Department of Justice is also requesting all unused triplicate forms be returned to the DOJ. This will enable the Department to retire the prescription series numbers from the electronic tracking system. Forms with expired validation dates may be destroyed by shredding or incineration. Forms with valid dates must be returned to the Department of Justice CURES program at the following address: 4949 Broadway Sacramento, California 95814.

In addition, effective January 1, 2005, pursuant to Health and Safety Code Section 11190 and Business and Professions Code Section 4170, all licensees who dispense Schedule II and III controlled substances must provide the dispensing information to the Department of Justice on a monthly basis by using the Prescribers' Direct Dispensing Log or the Direct Dispense Log for

veterinarians only. This information can also be received by the DOJ in electronic format by following specific Direct Dispense Data specifications provided by DOJ. Please visit the Attorney General's Website (http://ag.ca.gov/bne/content/trips.htm)

Additional information on the changes in prescribing laws is available on the Board of Pharmacy Web site: www.pharmacy.ca.gov and the Medical Board of California's Web site: www.caldocinfo.ca.gov.

As a reminder, please note that existing law provides physicians and pharmacist access to a an individual's history of controlled substances dispensed. This medical information, contained in the CURES data base within DOJ, is listed as a Patient Activity Report (PAR). Request forms for Patient Activity Report are located at the Attorney General's Website (http://ag.ca.gov/bne/content/trips.htm) under Criminal Justice, Bureau of Narcotic Enforcement, Programs, CURES.

Health and Safety Code Section 11167 states: In an emergency where failure to issue a prescription may result in loss of life or intense suffering, an order for a controlled substance may be dispensed on an oral order, an electronic data transmission order, or a written order not made on a controlled substance form as specified in section 11162.1, subject to all the following requirements:

- (a) The order contains all information required by subdivision (a) of Section 11164.
- (b) Any written order is signed and dated by the prescriber in ink, and the pharmacy reduces any oral or electronic data transmission order to hard copy form prior to dispensing the controlled substance.
- (c) The prescriber provides a written prescription on a controlled substance prescription form that meets the requirements of Section 11162.1, by the seventh day following the transmission of the initial order; a postmark by the seventh day following transmission of the initial order shall constitute compliance.
- (d) If the prescriber fails to comply with subdivision (c), the <u>pharmacy shall</u> so <u>notify the Bureau</u> of Narcotic Enforcement in writing <u>within 144 hours of the prescriber's failure to do so</u> and shall make and retain a hard copy, readily retrievable record of the prescription, including the date and method of notification of the Bureau of Narcotic Enforcement.